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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/647,777

12/29/2000

Hiroyuki Morimoto

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7590

10/05/2007

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

10/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/647,777

Applicant(s)

MORIMOTO ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-53,63-70 and 72-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-53,63-70 and 72-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/06/07 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-53, 63-70 and 72-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al. EP 0 650 826 A1, in view of Tsushima et al. US 6,036,974 and Roche US 5,075,114.

Morimoto teaches a tablet compressing method using tableting machine with lubricant spraying mean (see abstract). The method comprising spraying lubricant uniformly on the surface of an upper punch, a lower punch, and a die, filling the die with pharmaceutical materials, and compressing the pharmaceutical material to form a drug tablet (columns 2-3 and columns 5-7).

Morimoto does not explicitly teach the claimed lubricant such as stearic acid.

Tsushima teaches a method for preparation of tablet comprises preparing the tableting material containing medicines and excipients, coating on the surface of the tableting material a lubricant, coating the surface of the punches with lubricant (columns 2 and 6). Lubricant includes stearic acid and stearic acid metal salt (column 6, lines 51-60). Thus, it would have been obvious to one of ordinary skill in the art to modify the tableting method of Morimoto using stearic acid as a lubricant in view of the teaching of Tsushima, because Tsushima teaches the use of stearic acid as a lubricant is known in pharmaceutical art, because Tsushima teaches using stearic acid as a lubricant to coat the surface of the die and punch, and because Morimoto teaches the desirability of using lubricant to coat the die and punch of the tableting machine.

Morimoto further does not teach the specific form of pharmaceutical material being claimed, such as, coated granule or granule in a matrix base. Nonetheless, Morimoto teaches that his tableting method can be used for tableting many kinds of tablets such as powdered or granular medicine, and so on (column 7, lines 34-38).

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tableting machine having die wall and punches (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the pharmaceutical materials to be tableted in Morimoto using the coated drug granule in view of the teaching of Roche, because the references teach the use of compressed tableting machine to compress pharmaceutical materials.

Claims 42-53, 63-70 and 72-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsushima et al. US 6,036,974, in view of Roche US 5,075,114.

Tsushima teaches a method for preparation of tablet comprises preparing the tableting material containing medicines and excipients, coating on the surface of the tableting material a lubricant, coating the surface of the punches with lubricant, filling the die with the coated tableting material, and compressing to obtain tablet (columns 2 and 6). Lubricant includes stearic acid and stearic acid metal salt (column 6, lines 51-60).

Tsushima does not teach the specific form of pharmaceutical material being claimed, such as, coated granule in a matrix base.

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tableting machine having die wall and punches (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the tableting materials of Tsushima using the coated drug granule in view of the teaching of Roche, because the references teach the use of compressed tableting machine to compress pharmaceutical materials.

It is noted that the reference is silent as to the teaching of the percent amount of lubricant being coated onto the surface of the die and punches. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not

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inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable amount of lubricant to obtain a smooth surface tablet. As well as the dividing line on the tablet, it would have been obvious for one of ordinary skill in the art, because dividing line, groove line, marking line, or scored tablet is well known in pharmaceutical art. Moreover, absent of evident on the contrary, the burden is shifted to applicant to provide data showing the amount of surfactant uses by the cited references do not fall within the claimed range.

### ***Response to Arguments***

Applicant's arguments filed 10/24/06 have been fully considered but they are not persuasive.

Applicant admitted that Morimoto produces a tablet using a tableting machine with lubricant spraying means which can spray lubricant uniformly on the surface of an upper punch, a lower punch and a die, and Tsushima teaches preparing an aqueous tablet comprising 10% ethanol or water. However, applicant argues that the references, even taken together, do not teach or suggest a tablet which does not contain stearic acid or a stearic acid metal salt but which contains 0.0001-0.2 wt% stearic acid or stearic acid metal salt on the surface.

In response to applicant's argument, although Tsushima does not expressly teach the molding material does not contain any stearic acid or stearic acid metal salt,

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Tsushima throughout the patent does not teach adding lubricant in the internal phase. The examples disclosed in Tsushima do not suggest using lubricant in the molding material, but specifically disclosed that coating the surface of the tablet with a lubricant using stearic acid (example, and column 6, lines 51-58). Regarding Morimoto, as admitted by the applicant, Morimoto teaches the claimed method, however, Morimoto does not teach the claimed lubricant. Tsushima is cited in combination with Morimoto for the specific teaching of lubricant such as stearic acid or stearic acid metal salt.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAM  
PRIMARY EXAMINER



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